UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE: Acetaminophen - ASD-ADHD Products Liability Litigation	22md3043 (DLC) 22mc3043 (DLC) 22cv9052 (DLC) 22cv9880 (DLC)
This Document Relates To: Anderson, et al. v. Target Corp., et al., 22cv9052 Washington, et al. v. CVS Pharmacy, Inc., 22cv9880	OPINION AND ORDER

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DENISE COTE, District Judge:

In two separate actions, Makesha Anderson and Crystal Washington, individually and on behalf of their minor children (together, "Plaintiffs"), sue retailers of store-branded acetaminophen products. Washington brings her action against CVS Pharmacy, Inc. ("CVS"), and Anderson brings hers against Target Corp. ("Target") and Walmart Inc. ("Walmart")

(collectively with Target and CVS, "Defendants").[1] Anderson's and Washington's actions are members within this multidistrict litigation ("MDL") in which plaintiffs allege that in utero exposure to acetaminophen causes autism spectrum disorder ("ASD") and attention-deficit/hyperactivity disorder ("ADHD") in children. This Opinion addresses motions to dismiss Anderson's and Washington's claims on the grounds that the Defendants are protected by safe harbors under California and Texas law, respectively. For the following reasons, the motion to dismiss Anderson's claims is denied, and the motion to dismiss Washington's claims is granted.

Background

The following facts are drawn from the Plaintiffs' short form complaints ("SFCs") and the master complaint in this MDL that the SFCs incorporate by reference. The facts are taken as true for the purposes of this motion. The Court assumes familiarity with its prior Opinions in this MDL and summarizes only those facts relevant to this Opinion. In re Acetaminophen - ASD-ADHD Prods. Liab. Litig., No. 22md3043 (DLC), 2023 WL 3162623 (S.D.N.Y. Apr. 28, 2023) ("Apparent Manufacturer Opinion"); In re Acetaminophen - ASD-ADHD Prods. Liab. Litig.,

[1] Anderson also brings claims against drug manufacturer Johnson & Johnson Consumer Inc. ("JJCI").

No. 22md3043 (DLC), 2023 WL 3126636 (S.D.N.Y. Apr. 27, 2023) ("Misrepresentation Claims Opinion"); In re Acetaminophen - ASD-ADHD Prods. Liab. Litig., No. 22md3043 (DLC), 2023 WL 3126589 (S.D.N.Y. Apr. 27, 2023) ("Causation and Knowledge Opinion"); In re Acetaminophen - ASD-ADHD Prods. Liab. Litig., No. 22md3043 (DLC), 2023 WL 3045802 (S.D.N.Y. Apr. 21, 2023) ("TCPA and TPLA Opinion"); In re Acetaminophen - ASD-ADHD Prods. Liab. Litig., No. 22md3043 (DLC), 2023 WL 3026412 (S.D.N.Y. Apr. 20, 2023) ("April Preemption Opinion"); In re Acetaminophen - ASD-ADHD Prods. Liab. Litig., No. 22md3043 (DLC), 2022 WL 17348351 (S.D.N.Y. Nov. 14, 2022) ("November Preemption Opinion").

Anderson resides in California, and Washington resides in Texas. CVS is a resident of Rhode Island, Target is a resident of Minnesota, and Walmart is a resident of Delaware and Arkansas. While pregnant, Anderson and Washington both consumed acetaminophen products sold by the Defendants. Several studies have shown an association between prenatal exposure to acetaminophen and ASD and ADHD in children. Nonetheless, the labels for the Defendants' acetaminophen products at the relevant time did not mention the risk that a child could develop ASD or ADHD if the child's mother consumed acetaminophen while pregnant. The labels instead included pregnancy warnings that read: "**If pregnant or breast feeding**, ask a health

professional before use." (Emphasis in original.) Plaintiffs assert that, had they been warned of the risk of ASD and ADHD associated with acetaminophen products, they would have taken less acetaminophen or would not have taken it at all.

Anderson filed her action on July 27, 2022 in the U.S. District Court for the Northern District of California. On October 19, Washington filed her action in the U.S. District Court for the Northern District of Texas. On October 5, the Judicial Panel on Multidistrict Litigation consolidated several actions that asserted claims that prenatal exposure to acetaminophen causes ASD and ADHD in children and transferred the cases to this Court under 28 U.S.C. § 1407. Other actions, including Anderson's and Washington's, followed. On November 14, motions to dismiss two actions within the MDL on preemption grounds were denied. See November Preemption Opinion.[2]

At the November 17 initial pretrial conference, a schedule was set for the filing of two master complaints: one naming manufacturer Johnson & Johnson Consumer Inc. ("JJCI") and another naming CVS, Target, and Walmart, along with several other retailers (together, the "Retailer Defendants"). On

[2] The motion to reconsider this Opinion was denied on April 27, 2023. In re Acetaminophen - ASD-ADHD Prods. Liab. Litig., No. 22md3043 (DLC), 2023 WL 3126574 (S.D.N.Y. Apr. 27, 2023).

December 16, the MDL plaintiffs filed the master complaint against the Retailer Defendants.

On January 20, 2023, Anderson and Washington filed their SFCs. Anderson amended her SFC on February 3, and Washington amended hers on February 9. Anderson's SFC asserts claims against JJCI, Target, and Walmart under California law for strict liability for failure to warn, strict liability for design defect due to inadequate warnings and precautions, negligence, negligent misrepresentation, strict liability misrepresentation, breach of implied warranty, and violation of California's consumer protection laws. Washington's SFC asserts Texas state law claims against CVS for strict liability for failure to warn, strict liability for design defect due to inadequate warnings and precautions, negligence, negligent misrepresentation, strict liability misrepresentation, violation of Texas's consumer protection laws, breach of implied warranty, and liability as apparent manufacturer.

On February 10, the Retailer Defendants moved to dismiss all of the SFCs filed against them, including Anderson's and Washington's.[3] The motion became fully submitted on March 17.

[3] The Court has advised counsel that motions to dismiss should be brought against particular complaints and not against the master complaint. The master complaint is not the operative pleading; it is an administrative document. See Bell v. Publix Super Markets, Inc., 982 F.3d 468, 490 (7th Cir. 2020). The Retailer

Certain arguments raised in the motion to dismiss the claims against Retailer Defendants asserted in another action in this MDL were addressed in Opinions dated April 21 and April 28. See Apparent Manufacturer Opinion, 2023 WL 3162623; TCPA and TPLA Opinion, 2023 WL 3045802.

JJCI also moved to dismiss all the SFCs filed against it. Separate Opinions address the arguments raised in that motion. See Misrepresentation Claims Opinion, 2023 WL 3126636; Causation and Knowledge Opinion, 2023 WL 3126589; April Preemption Opinion, 2023 WL 3026412.

Discussion

I. Anderson's Action

Target and Walmart move to dismiss Anderson's claims on the ground that compliance with federal law is a defense under California law to the tort claims against them.[4] The motion to dismiss Anderson's claims on this ground is denied.

Defendants' motion has been styled as brought against all complaints filed in the MDL. The Court, therefore, has chosen the SFCs for this Opinion because the Retailer Defendants' motion to dismiss includes arguments directed specifically to California and Texas law, and these SFCs assert claims under those states' laws.

[4] For reasons explained in a prior Opinion in this litigation, California law applies to Anderson's claims. See Misrepresentation Claims Opinion, 2023 WL 3126636, at *4.

The defendants' argument is based primarily on an opinion from the California Supreme Court, Ramirez v. Plough, Inc., 863 P.2d 167 (Cal. 1993). Ramirez does not control here. In Ramirez, which arose on summary judgment, the court held that "a manufacturer may not be held liable in tort for failing to label a nonprescription drug with warnings in a language other than English." Id. at 168. The court explained that the issue presented in the case was

> not the existence of a duty to warn as such, or the class of persons to whom the duty extends, but the nature and scope of the acknowledged duty. Specifically, the issue is whether defendant's duty to warn required it to provide label or package warnings in Spanish.

Id. at 171 (emphases added). The defendant in Ramirez conceded, "at least for argument's sake, that it had a duty to warn purchasers of [the aspirin drug at issue] about the reported association between aspirin use" and the identified health condition. Id. Thus, Ramirez did not address whether a plaintiff can bring a products liability claim under California law against a drug retailer who failed to disclose a risk that it was not, under federal law, required to disclose.

The defendants have not sufficiently explained why the Court should read Ramirez more broadly to establish a general rule that compliance with federal law is a complete defense to all California tort claims based on drug labeling. A

significant portion of Ramirez's reasoning was based on the unique role that legislative and administrative bodies have played in defining "the circumstances under which warnings or other information should be provided in a language other than English." Id. at 174. Moreover, Ramirez explained that "[c]ourts have generally not looked with favor upon the use of statutory compliance as a defense to tort liability" and that the standards defined by statute and regulation are normally "minimum" standards that do "not prevent a finding that a reasonable person would have taken additional precautions where the situation is such as to call for them." Id. at 172. If Ramirez intended to announce a broad rule that plaintiffs cannot bring tort claims under California law for failure to warn of risks not required under federal law, the opinion would have stated as much and would not have addressed the plaintiff's alternative arguments for why the English label warnings were inadequate. Accordingly, Ramirez is not an adequate basis to dismiss Anderson's claims.[5]

[5] The defendants also point to certain sources indicating that California has adopted the federal regulations for nonprescription drugs as its own. See, e.g., Cal. Health & Safety Code Ann. § 110111. These sources define the scope of California's drug regulations, not a defendant's obligations under California tort law. Therefore, they are also not an adequate basis to dismiss Anderson's claims.

II. Washington's Action

Washington's claims are dismissed based on a Texas statutory safe harbor provision for defendants who label drugs in accordance with federal requirements. Before turning to the safe harbor provision, the appropriate choice of law is addressed.

A. Choice of Law

A multidistrict litigation transferee court "applies the substantive state law, including choice-of-law rules, of the jurisdiction in which the action was filed." Desiano v. Warner-Lambert & Co., 467 F.3d 85, 91 (2d Cir. 2006) (citation omitted). Washington's action was filed in Texas. Texas law uses the "most significant relationship" test from §§ 6 and 145 of the Restatement (Second) of Conflict of Laws (Am. L. Inst. 1971) to determine choice-of-law questions. Torrington v. Stutzman, 46 S.W.3d 829, 848 (Tex. 2000). Under this approach, courts consider certain "general factors," including:

(a) the needs of the interstate and international systems,

(b) the relevant policies of the forum,

(c) the relevant policies of other interested states and the relative interests of those states in the determination of the particular issue,

(d) the protection of justified expectations,

> (e) the basic policies underlying the particular field of law,
>
> (f) certainty, predictability and uniformity of result, and
>
> (g) ease in the determination and application of the law to be applied.

Id. (citation omitted). For tort cases, Texas courts also consider certain relevant contacts, including:

> (a) the place where the injury occurred,
>
> (b) the place where the conduct causing the injury occurred,
>
> (c) the domicile, residence, nationality, place of incorporation and place of business of the parties, and
>
> (d) the place where the relationship, if any, between the parties is centered.

Id. (citation omitted).

Texas law applies to Washington's claims. Washington and her child both reside in Texas. Washington purchased the products at issue in Texas. None of the considerations relevant to Texas choice-of-law analysis points to another state's law, and the parties do not dispute that Texas law should apply. The only connection to another state is that CVS is a resident of Rhode Island. Without more, this is insufficient to overcome the significant ties to Texas in Washington's case.

B. Safe Harbor

Washington's claims are dismissed because of Texas's safe harbor provision for drugs labeled in accordance with monographs developed by the U.S. Food and Drug Administration ("FDA"). The relevant Texas statute states in pertinent part:

> In a products liability action[6] alleging that an injury was caused by a failure to provide adequate warnings or information with regard to a pharmaceutical product, there is a rebuttable presumption that the defendant or defendants, including a healthcare provider, manufacturer, distributor, and prescriber, are not liable with respect to the allegations involving failure to provide adequate warnings or information if:
>
> . . .
>
> (2) the warnings provided were those stated in monographs developed by the United States Food and Drug Administration for pharmaceutical products that may be distributed without an approved new drug application.

Tex. Civ. Prac. & Rem. Code Ann. § 82.007(a) (emphases added). The statute articulates the ways to rebut the presumption, which are not relevant here. See id. § 82.007(b).

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[6] The statute defines "products liability action" as "any action against a manufacturer or seller for recovery of damages arising out of personal injury, death, or property damage allegedly caused by a defective product whether the action is based in strict tort liability, strict products liability, negligence, misrepresentation, breach of express or implied warranty, or any other theory or combination of theories." Tex. Civ. Prac. & Rem. Code § 82.001(2) (emphases added). There is no dispute that Washington's action is a products liability action within the meaning of the statute.

As described in greater detail in prior Opinions in this litigation, acetaminophen is regulated under the FDA's monograph system. See, April Preemption Opinion, 2023 WL 3026412, at *5-6; November Preemption Opinion, 2022 WL 17348351, at *4-6. In 1988, the FDA published a tentative final monograph regulating internal analgesic, antipyretic, and antirheumatic drug products, including acetaminophen, and from that date, regulated entities were required to comply with its terms. See Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use; Tentative Final Monograph, 53 Fed. Reg. 46204 (Nov. 16, 1988) ("IAAA TFM"). The parties agree that, when Washington purchased CVS's acetaminophen products, the products' labels included the pregnancy and breast-feeding warning that was required by the IAAA TFM and applicable regulations. As a result, under § 82.007(a), there is a rebuttable presumption that CVS is not liable. Washington does not allege any facts suggesting that she can rebut this presumption in one of the ways articulated in the statute. Accordingly, Washington's claims against CVS are dismissed.

Washington points out that, until 2020, when the Coronavirus Aid, Relief, and Economic Security Act, Pub. L. 116-136, 134 Stat. 281 (2020) made the IAAA TFM final, the IAAA TFM was only a "tentative monograph," with the legal status of a

proposed rule. She argues that, because the Texas statute uses the term "monograph" rather than "tentative monograph," her claims are not covered by the provision. This argument fails. Even though the IAAA TFM was only a tentative monograph when Washington purchased the CVS product during her pregnancy, the IAAA TFM was still a "monograph[] developed by the" FDA. See 21 C.F.R. § 330.10(a)(7)(i) ("[T]he Commissioner shall publish in the Federal Register a tentative order containing a monograph . . . ." (emphases added)). The statute does not distinguish between final and tentative monographs and applies equally to both. Thus, the safe harbor provision applies to Washington's claims.

Washington argues that applying the safe harbor to her claims requires a prediction of how the Texas Supreme Court would interpret the term "monograph" and that CVS has not properly addressed this prediction in its motion to dismiss. CVS has, however, addressed the plain meaning of the term "monograph." The Texas Supreme Court has explained that if a Texas "statute's plain meaning is unambiguous," it will "interpret its plain meaning, presuming that the Legislature intended for each of the statute's words to have a purpose and that the Legislature purposefully omitted words it did not include." Miles v. Tex. Cent. R.R. & Infrastructure, Inc., 647

S.W.3d 613, 619 (Tex. 2022) (citation omitted). It is thus safe to assume that the Texas Supreme Court's interpretation of the plain meaning of term "monograph" would not be limited to "final monographs." Although Washington asks the Court to read the requirement of finality into the safe harbor provision, she cites no lower court decisions, legislative history, or other materials suggesting that the Texas Supreme Court would interpret the statute in this way. And, indeed, the Texas Supreme Court has explained that it will "not impose its own judicial meaning on a statute by adding words not contained in the statute's language." Id. (citation omitted). Accordingly, there is no reason to believe that the Texas Supreme Court would hold that the term "monograph" includes only "final monographs."

Conclusion

The motion to dismiss Anderson's claims is denied. The motion to dismiss Washington's claims is granted.

Dated: New York, New York
May 15, 2023

DENISE COTE
United States District Judge